

CLAIMS

1. A solid pharmaceutical composition offering a dual release and comprising at least two
5 separate regions,

- a first region comprising at least one non-steroidal anti-inflammatory drug (NSAID) and an adequate pharmaceutical carrier containing a retardant material for an extended release delivery of said non-steroidal
10 anti-inflammatory drug (NSAID); and
- a second region comprising a stabilized gastroprotective prostaglandin and an adequate pharmaceutical carrier for an immediate release of said stabilized gastroprotective prostaglandin.

15 2. The pharmaceutical composition according to claim 1, wherein the first and the second regions are separated by a third region.

3. The pharmaceutical composition according to any one of the preceding claims, wherein the non-
20 steroidal anti-inflammatory drug (NSAID) is selected from the group consisting of aceclofenac, diclofenac, diflunisal, fenbufen, flufenamic acid, ibuprofen, indomethacin, ketoprofen, meclofenamate sodium, meloxicam, mefenamic acid, nabumetone, naproxen, piroxicam, suprofen,
25 tiaprofenic acid, acetylsalicylic acid, flurbiprofen, ketorolac, oxaprozin, sulindac, tenoxicam, tiaprofenic acid and suitable salts, esters, amides, prodrugs or analogues thereof.

4. The pharmaceutical composition according
30 to claim 1 to 3, wherein the retardant material of the first region is selected from the group consisting of lipidic materials, acrylic and methacrylic acid polymers and copolymers, cellulose-based polymers and a mixture thereof.

5. The pharmaceutical composition according to claim 1 to 4, wherein the prostaglandin is a "E-series" prostaglandin selected from the group consisting of PGE1, PGE2, misoprostol, enoprostol, enisoprost, rosaprostol, 5 miraprostol and analogues or derivatives thereof.

6. The pharmaceutical composition according to the claim 5, wherein the gastroprotective prostaglandin is misoprostol stabilized by a dispersion in hydroxypropylmethylcellulose (HPMC) or polyvinylpyrrolidone 10 (PVP).

7. The pharmaceutical composition according to any of the claims 1 to 6, which has a core tablet format comprising:

- a first region being a core containing a therapeutically effective amount of NSAID and a retardant material for an extended release delivery of the NSAID and,
- a second region being a mantle dry coating surrounding the core containing a therapeutically effective amount of a stabilized gastroprotective prostaglandin and a 20 pharmaceutical carrier for an immediate release of said stabilized gastroprotective prostaglandin.

8. The pharmaceutical composition according to any of the claims 1 to 6, which has a layered - or multilayered tablet format comprising:

- 25 - a first region being a first layer containing a therapeutically effective amount of NSAID and a retardant material for an extended release delivery of the NSAID and,
- a second region being a second layer containing a therapeutically effective amount of stabilized 30 gastroprotective prostaglandin and a pharmaceutical carrier for an immediate release of said gastroprotective prostaglandin and, optionally
- a third region being a third layer containing no active ingredient and separating the first and the second layers.

9. The pharmaceutical composition according to any of the claims 1 to 6, which has a multiple units tablet format comprising:

- a first region made of several units containing a therapeutically effective amount of NSAID and a retardant material for an extended release delivery of NSAID and,
- a second region made of a powder of one or several units containing a therapeutically effective amount of stabilized gastroprotective prostaglandin and a pharmaceutical carrier for an immediate release said stabilized gastroprotective prostaglandin.

10. The pharmaceutical composition according to any of the claims 1 to 6, which has a capsule format, preferably made of the Hydroxypropylmethylcellulose (HPMC) polymer and comprising:

- a first region made of one or several units containing a therapeutically effective amount of NSAID and a retardant material for an extended release delivery of NSAID and,
- a second region made of a powder of one or several units containing a therapeutically effective amount of stabilized gastroprotective prostaglandin and a pharmaceutical carrier for an immediate release of said of stabilized gastroprotective prostaglandin.

11. The pharmaceutical composition according to any of the preceding claims 1 to 6, wherein the non-steroidal anti-inflammatory drug (NSAID) is diclofenac, ketoprofen or naproxen and the stabilized gastroprotective prostaglandin is a stabilized misoprostol.

12. A method for the treatment and/or the prevention of inflammatory conditions or diseases in a mammal patient, including the human, that comprises the step of administrating a sufficient amount of the pharmaceutical composition according to any of the preceding claims 1 to 11, to said mammal patient.

13. The method according to claim 12, wherein said inflammatory condition or disease is osteoarthritis or rheumatoid arthritis.

14. The method of claim 12 or 13, wherein the
5 pharmaceutical composition is administrated as dual release formulation allowing a one a day or twice a day dosing into humans.

15. A packaging to minimize oxygen permeation, comprising the pharmaceutical composition
10 according to any of the claims 1 to 11 and an additional gastroprotective drug analogue medicament.